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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,765	12/17/2001	Derek Leigh Jones	10/009765	5113

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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,765	JONES, DEREK LEIGH	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *12-22 and 29-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,23-28 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-11, 23-28 and 34 in the reply filed on July 26, 2004 is acknowledged. The traversal is on the ground(s) that the amendments to the claims resulting in dependency on the compositions of claim 7 render the restriction requirement improper because a single invention is no being claimed. This is not found persuasive with regard to claims 12-17 because these claims recite spheroids in terms of a product defined by a specific process. Products may be made by materially different processes and yet be identical. There is nothing on the record to indicate that the spheroids produced using the product produced using the composition of claim 7 are patentably distinct from those produced by prior art methods, particularly since the spheroid-producing substance is absorbed to the culture vessel and appears to result in spheroid production by inhibiting cell attachment. When cell attachment is inhibited, as indicated in the prior art, spheroids are produced in suspension. The resultant spheroids are cell aggregates and do not appear to contain, within the boundary of the spheroid, the substance absorbed to the culture vessel walls. With regard to claims 18-22 and claims 30-32, no dependency or reference in the claims is made to the specific spheroid-forming composition of claim 7 and therefore the claims are not limited to the spheroid-forming composition of claim 7. However, the amendment to claim 29 does result in this claim being included with Group I.

The requirement is still deemed proper and is therefore made FINAL.

2. Where applicant elects claims directed to a product, and that product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Amendments to **process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). In order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims.

Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

Claims 1-11, 23-29 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a product obtained by the process comprising heating fetal calf serum to a temperature between 60°C and 80°C for between 30 minutes and 12 hours, does not reasonably provide enablement for claims to a "substance or mixture", a "polymeric protein comprising a polymer of one or more proteins containing in fetal calf serum, having a molecular weight in excess of 2MDA and having spheroid forming activity" or "a polymeric protein obtainable by heat treatment of fetal calf serum, whereby said polymeric protein is capable of spheroid forming activity" or for heat treatment "for a time and at a temperature sufficient to impart spheroid-forming activity". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Per the MPEP at 2164.01, any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement

was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies , Inc ., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The claims refers to the product obtained by the heat treatment of fetal calf serum as “a substance or mixture”, as a “polymeric protein comprising a polymer of one or more proteins containing in fetal calf serum, having a molecular weight in excess of 2MDA and having spheroid forming activity” and finally as “a polymeric protein obtainable by heat treatment of fetal calf serum, whereby said polymeric protein is capable of spheroid forming activity.” However, the specification provides no further documentation as to the type and nature of the protein; in fact, the only true measure of success is defined not by the physical nature of the product but is instead measured by its activity. Fetal calf serum contains numerous proteins and the specification does not indicate how these proteins are polymerized, whether they are a homogeneous polymer or a heterogeneous polymer, or the required length of the polymer. Further, it remains

unclear as to whether a single polymer is responsible for the activity or whether a mixture of polymers is required. Since fetal calf serum is normally used to promote attachment of cells to the culture vessel (see Blaauboer et al.), it remains unpredictable and therefore not enabled that one who would practice the invention could produce a polymerized protein from fetal calf serum and still have the reasonable expectation of success of obtaining spheroids in suspension in cell culture instead of attachment. The only way to provide this reasonable expectation of success is to subject a starting material (fetal calf serum) to a process (heat treatment between 60°C and 80°C for between 30 minutes and 12 hours). Therefore, claims must be limited to the product of the practice of a specific process.

With regard to that process, the specification states that there appear to be limits to the degree and time treatment of fetal calf serum in order to obtain the product that will cause the formation of cell spheroids during cell culture. While the specification suggest that other times and temperatures are contemplated, these suggestions are insufficient to provide the required amount of predictability and would cause one who would practice the claimed invention to engage in an undue amount of experimentation to determine which specific combinations of time and temperature (other than those specifically stated) would provide a reasonable expectation of success. For example, the specification states that incubation of fetal calf serum at temperatures at 60°C for four hours do not produce the product but an extended incubation time of seven hours at that temperature does produce the product. Those who would practice the invention would be unable, with the guidance of the specification, to produce a product that could

be reasonably be expected to be used to produce spheroids in culture at 60°C at 5 hours or 6 hours, but instead would need to engage in a trial-and-error evaluation which would be clearly considered an undue amount of experimentation. Similarly, times and temperatures outside the explicitly stated range would equally require a trial-and-error evaluation which would also equally be clearly considered an undue amount of experimentation.

3. Claims 23 and 26-28 provide for the use of a spheroid-forming substance or mixture and of a polymeric protein, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 23 and 26-28 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

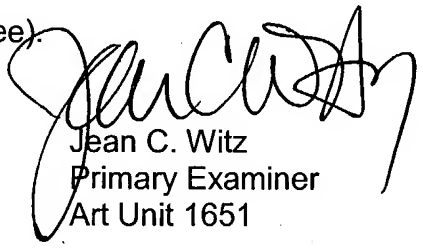
Allowable Subject Matter

4. As of the date of this office action, the claimed subject matter appears to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jean C. Witz
Primary Examiner
Art Unit 1651